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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,990	03/12/2007	Ettore Tallia	1011-784	3630
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HEDMAN & COSTIGAN, P.C. 1230 AVENUE OF THE AMERICAS 7th floor NEW YORK, NY 10020				
EXAMINER				
ROBERTS, LEZAH				
ART UNIT		PAPER NUMBER		
1612				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/562,990

Applicant(s)

TALLIA, ETTORE

Examiner

LEZAH ROBERTS

Art Unit

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicants' arguments in the Request for Continued Examination, filed on June 16, 2010, have been fully considered. Rejections not reiterated from previous office actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

The Amendment to the claims filed June 16, 2010 has been entered. New claim 15-18 are under consideration.

Claims

Claim Rejections - 35 USC § 103 – Obviousness

1) Claims 15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright (US 5,618,840) as evidenced by Shapiro et al. (Oral Microbiology and Immunology, 1994) in view of Kunz et al. (US 2002/0169138).

Wright teaches antibacterial oil-in-water emulsions (title). The emulsions are stable when heated or exposed to significant levels of acid and base (column 2, lines 56-57). The emulsions can be used in pharmaceutical preparations, made up of an

antibacterial emulsion and a pharmaceutically acceptable carrier (column 2, lines 58-65). Said preparations can be applied to oral surfaces, for example, as a mouthwash (column 3, lines 1-5). Oils useful in forming oily discontinuous phase of said emulsions include vegetable oils, such as soybean oil, canola oil, glycerol esters, flavor oils, such as peppermint oil, and mixtures thereof (column 2, lines 19-22). Peppermint oil is an essential oil that has anti-bacterial properties against bacteria in the oral cavity as evidenced by Shapiro et al. (Abstract) and therefore encompasses the limitation of an anti-bacteric substance in the oil phase. The compositions include cetylpyridinium chloride (a water soluble antiseptic substance encompassing a anti-bacteric in the water phase) (column 2, lines 29-32). The amounts of oil phase to water phase range from 1:4 to 1:2 on a volume to volume basis (column 4, lines 35-38).

Wright is silent about the visual appearance of the emulsions and the oils include aliphatic hydrocarbons, esters, alcohols and ethers.

Kunz et al. disclose delivery vehicles for bioactive agents and is used to disclose oils used in oil-in-water emulsions, encompassing claim 18. The compositions may be delivered orally (paragraph 0132). The vehicles include emulsions such as oil-in-water emulsions (paragraph 0116). The oils include vegetable oils, mineral oils, aromatic hydrocarbons, oils having animal origins, aliphatic hydrocarbons, aliphatic alcohols, triglycerides, and hydrocarbons comprising esters and ethers (paragraphs 0045-0054). The oils may also be used in mixtures (paragraph 0109). When the emulsions are diluted with water, they become cloudy (paragraph 0113) encompassing instant claim 15.

The reference differs from the instant claims insofar as it does not disclose the phase in which the active is dissolved or water soluble actives.

Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. It would have been obvious to one of ordinary skill in the art to have used the oils such as mineral oils, aromatic oils, aliphatic hydrocarbons, triglycerides, hydrocarbons comprising esters and ethers in mixtures in the oil phase in addition to those, such as peppermint oil, disclosed by Wright when formulating an oil-in-water mouthwash motivated by the desire to use oils suitable for use in the oil phase of oil-in-water emulsions as disclosed by Kunz et al. and supported by MPEP 2144.07.

As far as visual appearance is concerned, one skilled in the art would reasonably expect a formulation comprising oil and water phases combined in amounts described by the primary reference, encompassing those amounts recited by the instant claims, to be opaque. The disclosure of Kunz et al. further supports this reasoning by disclosing the addition of water causes the concentrated oil and water emulsions to become cloudy.

The prior art does not disclose the exact claimed values of 60% to about 95% aqueous phase and about 5% to 40% oil phase, but does overlap disclosing the oil and water phases in a 1:4 to 1:2 ratio: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Accordingly, since an overlap plainly exists here, it would have been obvious to have selected values within the overlap, consistent with the reasoning of the

Peterson decision.

Response to Applicant's Argument

In regard to Applicant's Arguments in regard to the film forming properties of the instant compositions in view of Wright and Kunz et al., Wright discloses an oil-in-water composition comprising an anti-bacterial component in each phase, a peppermint oil in the oil phase and cetylpyridinium chloride in the aqueous phase. Kunz et al. disclose components used in emulsions, which are the components recited in the instant claims. Although Kunz et al. does not disclose antibacterial or disinfecting agents, it does disclose component suitable to make the oil phase of an oil-in-water emulsion. Therefore it would have been obvious to modify the teachings of Wright with the teachings of Kunz et al. Therefore it would be reasonable to conclude that when the components of Kunz et al. are added to the compositions of Wright, that they would create a film on the teeth as asserted by Applicant.

2) Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright (US 5,618,840) as evidenced by Shapiro et al. (Oral Microbiology and Immunology, 1994) in view of Kunz et al. (US 2002/0169138), as applied to claims 15 and 18 above in further view of Panotti (EP 0244363).

Wright as evidenced by Shapiro et al. view of Kunz et al. is discussed above and discloses the composition may be used as mouthwashes. The combination of references differs from the instant claims insofar as it does not disclose the component in the water soluble phase of the oil-in-water composition.

Pianotti teaches an oral preparation in the form of mouthwashes or rinses (Page 3, line 24). The vehicle (e.g. pharmaceutically acceptable carrier, as described by the primary reference) is a water-alcohol mixture, present in the mouthrinse in an amount from 70 to 99.9% (page 3, lines 27-28), which is within the range for the aqueous phase recited by claim 15. Water soluble compounds that comprise said vehicle are inorganic fluoride salts (page 3, lines 53-54), saccharin (page 4, line 19), xylitol (page 4, line 16), as well as colorants (page 4, line 11), encompassing instant claims 16 and 17. Example 4 on pages 7 and 8 demonstrates a mouthrinse comprising ethanol, encompassing instant claim 17. Essential oils, also flavor oils, include thymol, eucalyptol, and menthol encompass aromatic oils.

The reference differs from the instant claims insofar as it does not disclose the compositions as emulsions and only discloses the aromatic oils as a component encompassed by the oil phase.

Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. It would have been obvious to one of ordinary skill in the art to have used the mouthwash composition comprising a water-alcohol mixture, fluoride, saccharine and xylitol as the aqueous pharmaceutical carrier when formulated into a mouthwash of

Wright as evidenced by Shapiro et al. view of Kunz et al. motivated by the desire to use a vehicle known in the art as suitable for mouthwashes, as disclosed by Pianotti. See by MPEP 2144.07.

Response to Applicant's Arguments

In regard to Applicant's arguments pertaining to Pianotti, Applicants claims recite the transitional language of "comprising" which is open language and therefore other components not recited by the instant claims are encompassed by the instant claims. The instant claims do not exclude the presence of essential oils and therefore essential oils may be included in the instant compositions along with the components recited in the instant claims.

Claims 15-18 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612